



**TEMPERATURE MAPPING PROTOCOL
FOR
COOLING INCUBATOR**

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**PROTOCOL
FOR
TEMPERATURE MAPPING
OF
COOLING INCUBATOR**

AREA: MICROBIOLOGY LAB (QA/QC BLOCK)

LOCATION: BET/MLT LAB

Document No.	
Supersedes	
Effective Date	
No. of Pages	



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1.0 Protocol Approval

This is a specific protocol for Temperature Mapping of Cooling Incubator, which is lying in the Incubator room, Microbiology lab (QA/QC Block).

Initial Approval

This protocol has been approved by the following

Prepared By:

Name	Designation	Department	Signature	Date

Checked By:

Name	Designation	Department	Signature	Date

Final Approval:

Name	Designation	Department	Signature	Date



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2.0 Overview

2.1 Objective

To establish the methodology for temperature mapping of Cooling Incubator (Equipment No.:) which is kept in the BET/MLT lab in Microbiology lab (QA/QC Block).

2.2 Purpose and Scope

The purpose of this protocol is to establish documentary evidence that Cooling Incubator (Equipment No.:) has been qualified to ensure uniformity of temperature at different locations for storage of the samples and other material.

This protocol is applicable for the temperature mapping of the Cooling Incubator (Equipment No.:) which is kept in the BET/MLT lab in Microbiology lab (QA/QC Block).

2.3 Responsibility

- **Protocol / Report Preparation:** Executive Microbiology
- **Protocol / Report checking :** Manager QC / Manager Maintenance/ Manager QA
- **Approval of Protocol / Report:** Head QA
- **Execution of Qualification Activity:** Executive Microbiology / Executive Engineering

2.4 Qualification Team

- Microbiologists/Executive Microbiology
- Engineering Executive / Manager
- Quality Assurance Executive / Manager



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3.0 Training Record:

3.1 Purpose

The purpose of the training is to familiarize the trainees with overall strategy of temperature mapping of Cooling Incubator (Equipment No.:).

3.2 Scope

This Training is applicable to the temperature mapping procedure of the Cooling Incubator Equipment No.-

3.3 Topics

The following topics shall be covered during training:

- Overall strategy of temperature mapping procedure.
- General precautions / guidelines to be followed during qualification.
- *Training record shall be attached with the report as Annexure – 01.*



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4.0 Pre – Qualification Requirements

Following instruments shall be required for the temperature mapping of the Cooling Incubator (.....).

S.No.	Instrument Name	Instrument Code / S.No.	Calibration Certificate No.	Calibration Due On
1.	Data logger			
2.	Temperature Sensors			
3.	Temperature Sensors			
4.	Temperature Sensors			
5.	Temperature Sensors			
6.	Temperature Sensors			
7.	Temperature Sensors			
8.	Temperature Sensors			
9.	Temperature Sensors			
10.	Temperature Sensors			
11.	Temperature Sensors			
12.	Temperature Sensors			
13.	Temperature Sensors			
14.	Temperature Sensors			
15.	Temperature Sensors			
16.	Temperature Sensors			
17.	Temperature Sensors			
18.	RTD Sensor (Inbuilt)			

Calibration Certificate shall be attached as **Annexure-02**.



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5.0 System/Equipment Description:

5.1 System/Equipment details

The Cooling Incubator shall be used to store the test samples and other material at temperature 2-8° C.

5.2 System /Equipment Identification

Component	Specifications
Name of equipment	Cooling incubator
Model	
Serial Number	
Tag No.	
Name of the Supplier	Newtronic Equipment Company Pvt. Ltd.
Chamber size	900 mm (H) x 600 mm (W) x 600 mm (D)
Temperature range	2 to 8° C
Temperature display	Digital with readability of 0.1 °C
Trays	3 Nos. - Perforated
Tray Size	550 x 550 mm
Door	Double wall metal door, magnetic gasket and lock
Controller	Programmable Logic Controller (PLC), Make-Schneider
PLC Model No.	
Human Machine Interface (HMI) Model No.	
Control Panel	Panel at front top to view and set temp. real time clock
Temperature sensor	PT 100 type, Make Simplicon
Equipment Location	Microbiology laboratory (QA/QC Block)
Material of Construction	
Internal Chamber	SS 304
External Chamber	SS 304
Trays	SS 304
Insulation	PUF insulation between outer chamber and inner chamber



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6.0 Temperature Mapping Procedure

The following procedure shall be used for temperature mapping of Cooling Incubator.

- 6.1 Location of temperature sensors in chambers shall be as shown in the diagram given in **Exhibit – E01**.
- 6.2 16 No. of sensors shall be used for the temperature mapping
- 6.3 One sensor shall be placed at each corner of each shelf and one in the middle.
- 6.4 One sensor shall be placed parallel to the inbuilt sensor.
- 6.5 Set the recording / printing interval as 30 Minutes in data loggers.
- 6.6 Close the door of Incubator.
- 6.7 Now start recording temperature.
- 6.8 Record the temperature profile of the equipment for not less than 24 hours.
- 6.9 Take the print out of the data.
- 6.10 Observations of the temperature mapping shall be recorded as per **Exhibit – E02**.
- 6.11 **Acceptable criteria:** Temperature variation at different locations shall not be more than $5.0 \pm 2.0^\circ \text{C}$.
- 6.12 Any deviation observed during Temperature mapping shall be recorded as per **Clause 10.0**.
- 6.13 Observed deviation shall be reported to the Department Head and Quality Head.
- 6.14 If the observed deviation does not have any major impact on the Temperature mapping study the final conclusion shall be provided.
- 6.15 If the observed deviation has major impact on the Temperature mapping, deviation shall be reported to the manufacturer for the corrective action and mapping activity shall be done again.



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7.0 Acceptance Criteria

Temperature mapping shall be considered acceptable when requirements listed in section 6.0 of this protocol has been fulfilled and Cooling Incubator is performing as per intended purpose.

8.0 Qualification Report

The Temperature mapping report shall consist of a summary document, in narrative form, which shall briefly describe the activity performed along with the observations recorded in relevant exhibits.

This report shall also include the related documents and attachments / annexure which were completed at the time of qualification activity.

9.0 Approval of Qualification Report

The report shall be evaluated and proper references / conclusions / recommendations shall be recorded by quality assurance.

The Re- qualification report shall be evaluated and finally approved by quality assurance.



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10.0 Observed Deviation

S.No.	Page No.	Point No.	Observed Deviation	Deviation Reported By	Deviation Approved By	Corrective Action Taken	Justification of Corrective Action	Corrective action taken and justification given by	
Report Approved By									
Department Head						Quality Head			



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11.0 List of Exhibits / Annexure

11.1 List of Exhibits

Exhibit No.	Exhibit Title	No. of Pages
E01	Diagram Showing Locations of temperature probes in Cooling Incubator	
E02	Temperature mapping record	
Total No. of Pages		

11.2 List of Annexure

Annexure No.	Annexure Title	No. of Pages
01	Training Record	
02	Calibration certificates	
03	Printouts of Data logger	
Total No. of Pages		

12.0 Reference Documents (If Any)

NA

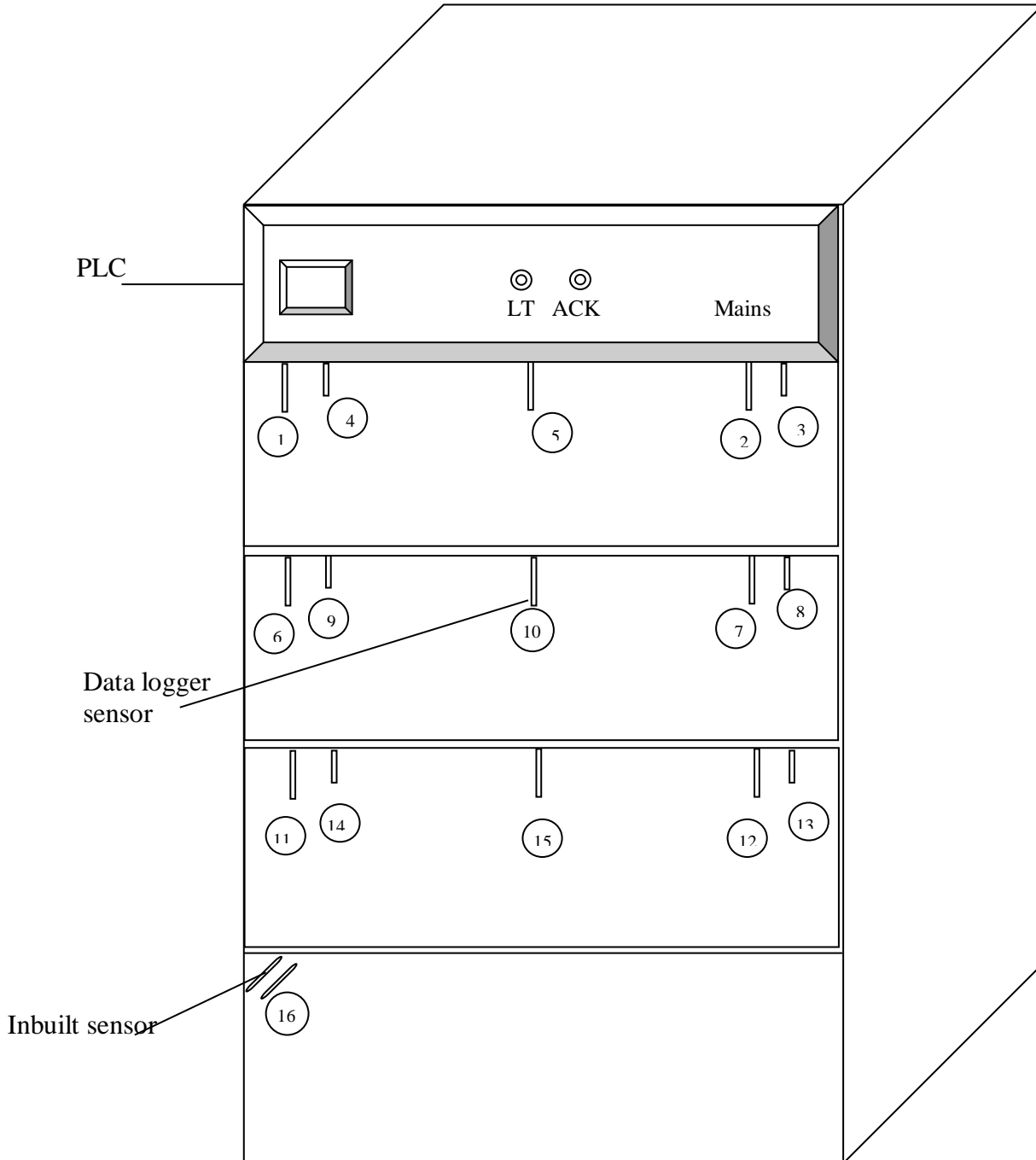


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Exhibit – E01

Diagram Showing Locations of Temperature Probes in Cooling Incubator



1 to 16 No. is sensors of External data logger.

Checked By: _____
(QC) (Name) (Sign) (Date)

Verified By: _____
(QA) (Name) (Sign) (Date)



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Exhibit – E02

Temperature Mapping Record

Mapping started on:

Set Temperature (°C):

Holding time started at/Date:

Holding time ended at/Date:

Probe Description	Minimum Temperature (°C)	Maximum Temperature (°C)	Average Temperature (°C)	Remarks
Probe 1				
Probe 2				
Probe 3				
Probe 4				
Probe 5				
Probe 6				
Probe 7				
Probe 8				
Probe 9				
Probe 10				
Probe 11				
Probe 12				
Probe 13				
Probe 14				
Probe 15				
Probe 16				

Acceptance Criteria – Temperature at any location shall not show variation more than 5.0 ± 2 °C.

Remarks: Temperature at all the locations **is within/is not within** acceptance criteria.

Checked By: _____
 (QC) (Name) (Sign) (Date)

Verified By: _____
 (QA) (Name) (Sign) (Date)



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Annexure – 01

Training Record

Equipment Name:	Cooling Incubator
Equipment No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	



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**Annexure – 02
Calibration Certificates**

Equipment Name:	Cooling Incubator
Equipment No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	



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Annexure – 03

Print outs of Data logger

Equipment Name:	Cooling Incubator
Equipment No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	